

REMARKS

Claims 1 and 51 are cancelled without prejudice. Claims 41, 68, and 69 are amended; marked up versions of the amended claims are attached hereto pursuant to 37 C.F.R. § 1.121(c)(ii). Claims 41-50, 52-55, and 68-78 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

The Examiner objected to the abstract because it exceeds 150 words. In response, applicants amended the abstract to reduce its length. A substitute abstract is attached herewith.

The drawings were objected to under 37 C.F.R. § 1.83(a) because they allegedly did not show "mixing device," "mixer," "mixing chamber," the "first inlet," the "second inlet," and their arrangement with the "mixing chamber." The Examiner requested that all of the features listed above be shown in the drawings or the features be canceled from the claims. The specification is also objected to as failing to provide proper antecedent basis for the "mixing device," "mixer," "mixing chamber," the "first inlet," the "second inlet," and their arrangement with the mixing chamber.

In response, applicants propose to amend Figures 7A and 7D as indicated in red to show the second inlet **670**. The specification has also been amended as shown above to include the reference numeral **670**. The limitations "mixing device" and "mixer" have been removed as unnecessary. The "mixing chamber" **612**, outlet **614**, and the "first inlet" **646** are shown in Figures 6 and 7. Pages 48 and 49 of the specification have also been amended to clarify that an interior space **612** shown in Figures 6 and 7 is an embodiment of a mixing chamber, and port **646** is an embodiment of a first inlet. Also, Figures 6 and 7 illustrate an arrangement of the inlets and the outlet on the mixing chamber in accordance with one embodiment of the present invention. Applicants believe that the proposed changes overcome the objections to the drawings and the specification.

The Examiner objected to the use of the trademark AKZO OXYPHAN™, because it was not capitalized and allegedly was not accompanied by the generic terminology. In response, applicants amended the specification as shown above by capitalizing the trademark. However, applicants would like to point out that the original specification already included the required generic terminology ("polypropylene hollow fiber mat including 16.8 fibers/cm") describing the trademarked product (page 38, lines 16-17). Accordingly, applicants submit that the use of the

trademark in the instant specification fully satisfies the requirements stated by the Examiner and, thus, the rejection should be removed.

Claim 51 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for using the phrase "being arranged to create a vortical flow." This rejection is moot due to the cancellation of the claim.

Claims 1, 41-45, 47-50, 52-54, 68, and 70-72 are rejected under 35 U.S.C. § 102(e) as being anticipated by Divino, Jr. et. al., U.S. Patent No. 6,180,059. This rejection is moot with respect to cancelled claim 1. With respect to the claims 41-45, 47-50, 52-54, 68, and 70-72, the rejection is respectfully traversed.

A request is hereby made for correction of the filing status of the present invention to make it a continuation-in-part of U.S. Patent Application Ser. No. 09/122,143, which issued on January 30, 2001 as U.S. Patent No. 6,180,059 (the '059 patent). The present patent application was filed while the '059 patent was pending. The present patent application and the '059 patent share a common inventor, Mr. Vincent Divino, Jr. Also, the instant specification has been amended to add cross-references to the '059 patent. Accordingly, the present patent application, as amended, is entitled to claim priority from the '059 patent under Rule 1.78(a). Since applicants amended the application to claim priority from the '059 patent, the '059 patent should be withdrawn as a prior art reference. Accordingly, applicants request withdrawal of the rejection based thereupon.

Claims 1, 41-45, 47, 48, 50, 53-55, and 68-75 are rejected under 35 U.S.C. § 102(b) as being anticipated by Grady, U.S. Patent No. 5,084,011 (the '011 patent). This rejection is moot with respect to cancelled claim 1. With respect to the claims 41-45, 47, 48, 50, 53-55, and 68-75, the rejection is traversed.

Independent claims 41 and 68 have been amended by incorporating the subject matter of claim 51, which is now cancelled. Since claim 51 was not rejected over the '011 patent, amended claims 41 and 68 are also patentable over the '011 patent.

Indeed, both independent claims 41 and 68 have been amended to require that a first fluid enters into the mixing chamber via the first inlet and flows vortically within the mixing chamber. As explained on page 21, lines 5-10, of the specification, in the present invention, blood is enriched with a gas as a result of its convective mixing with an oxygen-supersaturated fluid and liquid-to-liquid gas diffusion. Accordingly, a particular positioning of the inlets for the blood and the oxygen-supersaturated fluid is required in order to promote mixing and rapid gas transfer (page 21, line 20 - page 22, line 4).

The '011 patent does not anticipate or make the amended claims 41 and 68 obvious because it does not teach or suggest the liquid-to-liquid oxygenation method in which a first fluid enters a mixing chamber and flows vortically, and with which a gas-supersaturated fluid enters the mixing chamber and mixes. Instead, the '011 patent teaches a conventional gas-to-liquid oxygenation in which both the oxygen gas and the blood to be oxygenated enter a pressure vessel **34** of the gas/liquid contact apparatus from the top, in a downward direction. Therefore, claims 41 and 68 are neither anticipated nor are rendered obvious by the '011 patent. Claims 42-45, 47, 48, 50, 53-55, and 69-75, depend from claims 41 and 68 and are patentable for at least the same reasons.

Claims 5 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '059 patent in view of Spears, U.S. Patent No. 5,693,017 (the '017 patent). This rejection appears to be a typographical error, since claims 5 and 27 are not pending in the instant application.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1769.

Respectfully submitted,

Date: January 16, 2003

A handwritten signature in cursive script, reading "Margaret A. Kivinski".

Margaret A. Kivinski, Esq.

Registration No. 38,517

Attorney for Applicant(s)

TherOx, Inc.

2400 Michelson Drive

Irvine, California 92612

Phone: 949-757-1999

Fax: 949-757-1989

**VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE SPECIFICATION**

Page 2, before the paragraph entitled "Field of Invention," please replace the first paragraph with the following text:

--RELATED APPLICATIONS

This application is a [C]continuation of U.S. Patent A[a]pplication Serial No. 09/410,344 filed [09/30/99]September 30, 1999, which is incorporated herein by reference. This application is also a continuation-in-part of U.S. Patent Application Serial No. 09/122,143 filed July 24, 1998, now U.S. Patent No. 6,180,059B1, which is incorporated herein by reference. --

Please replace the text of the second full paragraph on page 38, lines 11-18, with the following text:

The hollow fibers **70** advantageously comprise a 160 cm length of matted fibers (each fiber advantageously about 8-10 cm in length) loosely rolled into a cylindrical shape, so that about a 0.05 inch space remains between the outer diameter of the fiber roll and the inner diameter of the oxygenator housing. The ends of the fibers proximate the entrance and exit manifolds advantageously are open and clean. A particularly advantageous matted fiber commercially available for use is the [Akzo OxyphanTM] AKZO OXYPHANTM fiber mat, a polypropylene hollow fiber mat including 16.8 fibers/cm, each having a wall thickness of about 50 μ m and about a 280 μ m inner diameter, available from Akzo Nobel, Germany.

Please replace the second paragraph on page 48 with the following text:

Turning now to Figure 6, an extracorporeal blood oxygenation circuit is shown including a pump assembly **500** operable to deliver blood withdrawn from a patient to an exemplary liquid-to-liquid oxygenation assembly **600**. The assembly **600**, portions of which are shown in greater detail in Figures 7A-E, advantageously includes an injector housing **610**, a sidewall assembly **620**, and a cap **630** joined so as to define an interior space (also referred to as a mixing chamber) **612** within which blood provided by the supply tube **640** mixes with oxygen-supersaturated fluid provided by the capillary assembly **650** to form oxygenated blood. The oxygenated blood exits the interior space **612** via outlet **614** for delivery via return tube **660** to a fluid delivery apparatus **510**. The injector housing **610**, sidewall assembly **620**, cap **630**, and other assembly components advantageously are

disposable and are made of biocompatible materials, e.g., polycarbonate, polyethelyene and the like. The tubing advantageously comprises medical grade PVC tubing.

Please replace the first and the second paragraphs on page 49 with the following text:
passageway **644** extending through at least a portion of the housing **610** and including a fluid port (also referred to as a first inlet) **646**. Advantageously, blood [exits] enters the mixing chamber **612** through port **646** so as to create a vortical or cyclonic flow within the [interior space] mixing chamber **612**, e.g., along a path substantially tangential to the chamber wall.

The capillary assembly **650** advantageously includes a single fused silica capillary having a 100 μm inner diameter and a 350 μm outer diameter, which comprises a continuous fluid pathway between a first end of the assembly **650** operatively coupled to the outlet of an oxygen-supersaturated fluid supply assembly **550** and a second end of the assembly **650** disposed to allow fluid exiting the capillary to enter the interior space **612** of the liquid-to-liquid oxygenator through a second inlet **670**. Advantageously, the capillary assembly **650** includes between its first and second ends a luer fitting **652** for securing the capillary in place upon being positioned within a lumen **654** passing through at least a portion of the injector housing **610** to the interior space **612**. The capillary assembly advantageously may further include a support assembly (e.g., a rigid tube within which at least a portion of the capillary is disposed) proximate the second end of the assembly **650** to help maintain the capillary fluid outlet port in place within the interior space **612**, and/or a strain relief assembly (e.g., a flexible tube within which at least a portion of the capillary is disposed) to help prevent excessive bending or kinking of the capillary.

IN THE CLAIMS

Please replace the text of claims 41, 68, and 69 with the following text:

41. (Amended) A method for forming a gas-enriched fluid comprising the acts of:
providing a [mixer having an internal] mixing chamber having a first inlet, a second inlet, and an outlet;

delivering a first fluid to the mixing chamber [of the mixer] via the first inlet, wherein the first fluid enters the mixing chamber and flows vortically within the mixing chamber; and

delivering a second fluid having a liquid phase supersaturated with a gas to the mixing chamber [of the mixer] via the second inlet to mix with the first fluid and form the gas-enriched fluid.

68. (Amended) A blood oxygenation method comprising the act of:
extracorporeally mixing blood flowing vortically in a mixing chamber and an oxygen-supersaturated fluid to effect direct liquid-to-liquid oxygenation forming oxygen-enriched blood.

69. (Amended) The method, as set forth in claim 68, wherein the mixing [occurs within] chamber is a pressurizable chamber.